

November 4, 1997

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204



Dear Sir/Madam,

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that SmithKline Beecham Consumer Healthcare, Pittsburgh, PA 15230, within the past 30 days commenced marketing a dietary supplement bearing the following statement(s) on the label and/or in the labeling:

TEXT OF CLAIMS

- "Naturally helps improve performance"
- "Helps endurance"
- "Assists oxygen circulation"
- "For every day energy and vitality"
- ".. works naturally to promote overall performance and endurance."
- "... can be used as a daily supplement to help you meet the demands of everyday life"
- ".. has been used for generations to help maintain normal body functions."
- "Panax ginseng is considered a natural "adaptogen". An "adaptogen" is a product that helps build vitality, while strengthening normal body functions."

NAME OF INGREDIENT OR SUPPLEMENT THAT IS SUBJECT OF CLAIM Extract of *Panax ginseng* (root)

NAME OF SUPPLEMENT (INCLUDING BRAND NAME)

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The undersigned certifies that the information contained in this notice is complete and accurate and that SmithKline Beecham Consumer Healthcare has substantiation that the statements are truthful and not misleading.

If you have any questions, feel free to contact me at (973) 631-8179 or at the address below.

Sincerely,

Sue E. James

Associate Director, Regulatory Affairs

975-0162

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